K042805 Attachment 4

DEC 16 2004

PERUSAHAAN GETAH ASAS SDN. BHD.

(Company No: 89708-V)

Ammended Copy

FDA 510(k), Premarket Notification : 510(k) Summary of Safety and Effectiveness Information

1.0 Submitter:

Perusahaan Getah Asas Sdn Bhd
Lot 1365, Batu 17, Jalan Sungai Sembilang,
45800 Jeram,
Selangor Darul Ehsan,
Malaysia

Telephone No.: +603 3264 0787
Fax No.: +603 3264 0644

2.0 Contact Person:

Contact: Mr Kong Chang **TAN**
Telephone No.: +603 3291 1949
Fax No.: +603 3291 2903

3.0 Name of Device:

Trade Name: Powder Free Nitrile Patient Examination Glove, Blue Colored Non-Sterile (Low Dermatitis Potential and Chemotherapy Drug Protection Labeling Claim)
Common Name: Patient Examination Glove
Classification Name: Patient Examination Glove

4.0 Identification of The Legally Marketed Device:

The Powder Free Nitrile Patient Examination Glove, Blue Colored Non-Sterile (Low Dermatitis Potential and Chemotherapy Drug Protection Labeling Claim), Class I patient examination gloves, Nitrile-80LZC, meets all of the requirements of ASTM D 6319-00a$^{\varepsilon 3}$ Standard Specification for Nitrile Examination Gloves for Medical Application.

5.0 Description of Device:

The Powder Free Nitrile Patient Examination Glove, Blue Colored Non-Sterile (Low Dermatitis Potential and Chemotherapy Drug Protection Labeling Claim) will meet all the current specification for ASTM D 6319-00a$^{\varepsilon 3}$.

6.0 Intended Use of the Device:

The Powder Free Nitrile Patient Examination Glove, Blue Colored Non-Sterile (Low Dermatitis Potential and Chemotherapy Drug Protection Labeling Claim) is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.
The glove may provide additional protection in other areas where users are handling certain hazardous chemicals such as commonly used chemotherapy drugs, as penetration and permeation by these drugs are resisted.

7.0 Summary of The Technological Characteristics of The Device:

The Powder Free Nitrile Patient Examination Glove, Blue Colored Non-Sterile (Low Dermatitis Potential and Chemotherapy Drug Protection Labeling Claim) possesses the following technological characteristic (as compared to ASTM or equivalent standards):

Characteristic	Standards	Device Performance
Dimensions	ASTM D 6319-00a$^{\varepsilon 3}$	Meets
Physical Properties	ASTM D 412-98	Meets
Freedom from pin-holes	ASTM D 5151-99	Meets
Powder Free Residue	ASTM D 6124-01	Meets
Biocompatibility	Dermal Sensitization (as per ASTM F-720-81)	Not a contact skin sensitizer
	Primary Skin Irritation Test (as per 16 CFR Part 1500)	Not a primary skin irritant
	Cytotoxicity Test (as per ISO 10993-5)	Non cytotoxic
Low Dermatitis Potential	Modified Draize Test	Did not induce clinically significant skin irritation nor show any evidence of induced allergic contact dermatitis in human subjects.

Characteristic	Standards	Device Performance
Chemotherapy Drugs Permeation Test	ASTM F 739	Chemotherapy Drug Permeation (average normalized breakthrough time in minutes) Carmustine (3.3 mg/mL) 137 Cisplatin (1.0 mg/mL) >240 Cyclophosphamide (20.0 mg/mL) >240 Dacarbazine (DTIC) (10.0 mg/mL) >240 Doxorubicin Hydrochloride (2.0 mg/mL) >240 5-Fluorouracil (50.0 mg/mL) >240 Etoposide (20.0 mg/mL) >240 Paclitaxel (Taxol) (6.0 mg/mL) >240 Thio-Tepa (10.0 mg/mL) >240

8.0 Substantial Equivalent Based on Assessment of Non-Clinical Performance Data

The performance test data that support a determination of substantial equivalence are described above.

9.0 Substantial Equivalent Based on Assessment of Clinical Performance Data

Clinical data are not needed for examination gloves.

10.0 Conclusion

It can be concluded that the Powder Free Nitrile Patient Examination Glove, Blue Colored Non-Sterile (Low Dermatitis Potential and Chemotherapy Drug Protection Labeling Claim) is safe and effective for use with chemotherapeutic agents and will perform according to the glove performance standards referenced in Section 7 above, thereby meeting ASTM standards, FDA requirements, and the labeling claims for the product.
Consequently, this device is substantially equivalent to current marketed devices. This summary will include any other information reasonably deemed necessary by the FDA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 16 2004

Mr. KK Leong
Quality Assurance/ Regulatory Affairs Manager
Perusahaan Getah Asas Sdn. Bhd.
Lot 1365, Batu 17, Jalan Sungai Sembilang,
45800 Jeram,
Selangor Darul Ehsan,
MALAYSIA

Re: K042805
Trade/Device Name: Powdered Free Nitrile Patient Examination Gloves, Blue Colored Non-Sterile (Low Dermatitis Potential and Chemotherapy Drug Protection Labeling Claims)
Regulation Number: 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZC
Dated: December 2, 2004
Received: December 8, 2004

Dear Mr. Leong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

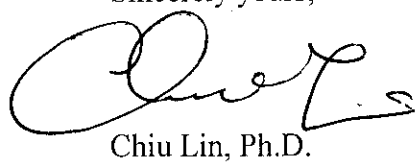
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042805

Device Name: Powder Free Nitrile Patient Examination Gloves Colour Blue Non-Sterile (with Low dermatitis Potential and Chemotherapy Drugs Protection Labeling Claims)

Indications For Use: A Powder Free Nitrile Patient Examination Glove is a dispoable device intended to be worn on the hand for medical purposes to provide a barrier against potentially infectious materials and other contaminants. In addition, these gloves are worn to protect against exposure to some chemotherapy drugs.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use X (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Julie Mechan MD 12-15-04

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K042805